



December 17, 2025

Shenzhen Comen Medical Instruments Co., Ltd.  
Charlotte Lin  
Registration Engineer  
Fl 10, Fl 11 and Sec C of Fl 12 of Bldg 1A & Fl 1 to Fl 5  
of Bldg 2, FIYTA Timepiece Bldg, Nanhuan Ave Matian Sub-dist  
Shenzhen, 518106  
China

Re: K250854

Trade/Device Name: Multi-parameter Patient Monitor (N10); Multi-parameter Patient Monitor (N12);  
Multi-parameter Patient Monitor (N15); Multi-parameter Patient Monitor  
(N10MPro); Multi-parameter Patient Monitor (N12MPro); Multi-parameter  
Patient Monitor (N15MPro)

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Regulatory Class: Class II

Product Code: MHX, DSI, MLD, DSJ, DSK, DXN, DRT, MLC, DQA, DSB, MUD, MSX, KRC, DSF,  
DRS, FLL, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, KOI, OLV, OLT,  
OMC, ORT

Dated: March 19, 2025

Received: March 21, 2025

Dear Charlotte Lin:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical->

[devices/device-advice-comprehensive-regulatory-assistance](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JENNIFER W. SHIH -S

Jennifer Kozen  
Assistant Director  
Division of Cardiac Electrophysiology,  
Diagnostics, and Monitoring Devices  
Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K250854

Device Name

Multi-parameter Patient Monitor (N10);  
Multi-parameter Patient Monitor (N12);  
Multi-parameter Patient Monitor (N15);  
Multi-parameter Patient Monitor (N10MPro);  
Multi-parameter Patient Monitor (N12MPro);  
Multi-parameter Patient Monitor (N15MPro)

Indications for Use (Describe)

The N10, N12, N15, N10MPro, N12MPro, NM15Pro Multi-parameter Patient Monitors are intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 12-lead selectable), Arrhythmia Analysis, ST Segment Analysis, QT Analysis, Heart Rate (HR) and Heart-Rate-Variability(HRV)), interpretations of resting 12-lead ECG, Respiration rate(Resp), Temperature(Temp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), Carbon Dioxide (CO2). The N10MPro, N12MPro, NM15Pro Multi-parameter Patient Monitors are also intended for monitoring, displaying, reviewing, storing, alarming and transferring of physiological parameters including Masimo Rainbow SpO2, Anesthesia gas (AG), oxygen (O2) respiratory gas monitoring, Bispectral Index (BIS), Respiration Mechanics (RM) and Neuromuscular Transmission Monitoring (NMT). All the parameters can be monitored on single adult, pediatric, and neonatal patient except for the following:

- Arrhythmia analysis is intended to use on adult patients only and is not intended and shall not be used on pediatric and neonatal population.
- NIBP measurement continual mode is not applicable to neonates.
- When using COMEN SpO2, the monitor is intended to be used on adult patient only.
- PAWP is intended for adult and pediatric patients only.
- C.O. measurement is intended for adult patients only.
- BIS monitoring is intended for adult patients only.
- RM is intended for adult and pediatric patients only.
- NMT monitoring is intended for adult and pediatric patients only.

The monitors are to be used in healthcare facilities by healthcare professionals or under their guidance.

The Multi-parameter Patient monitors are not intended for emergency and transport use, aircraft environment or home use.

The monitors are not intend for use as apnea monitors.

The monitors are not intended for use in MRI or CT environments.

The monitors are not used on patients who have a demonstrated need for cardiac monitoring known arrhythmias of VT, Accelerated Idioventricular rhythm and Torsades de Pointes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 510(k) Summary

N10, N12, N15, N10MPro, N12MPro and N15MPro Multi-parameter Patient Monitor

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92.

## 1. Submitter

**Date:** 17 December 2025

**Submitter:** Shenzhen Comen Medical Instrument Co., Ltd.

**Address:** Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, China.

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## 2. Device

**Device trade name:** Multi-parameter Patient Monitor (N10, N12, N15, N10MPro, N12MPro and N15MPro)

**Common name:** Multi-parameter Patient Monitor

**Classification name:** 21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)

**Regulatory Class:** Class II

**Primary Product code:** MHX - Monitor, Physiological, Patient (with arrhythmia detection or alarms)

Table 1: Secondary Product Codes

Device Panel	Regulation number & Classification	Product code	Description
Cardiovascular	§870.1025, II	DSI	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Cardiovascular	§870.1025, II	MLD	Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Cardiovascular	§870.1100, II	DSJ	Alarm, Blood-Pressure
Cardiovascular	§870.1110, II	DSK	Computer, Blood-Pressure
Cardiovascular	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
Cardiovascular	§870.2300, II	DRT	Monitor, Cardiac (Including

Device Panel	Regulation number & Classification	Product code	Description
			Cardiotachometer & Rate Alarm)
Cardiovascular	§870.2340, II	MLC	Monitor, ST segment
Anesthesiology	§870.2700, II	DQA	Oximeter
Cardiovascular	§870.2770, II	DSB	Plethysmograph, Impedance
Cardiovascular	§870.2770, II	MUD	Oximeter, tissue saturation
Cardiovascular	§870.2300/II	MSX	Cardiac monitor (including cardiotachometer and rate alarm).
Cardiovascular	§870.2370, II	KRC	Tester, electrode, surface, electrocardiographic
Cardiovascular	§870.2810, I	DSF	Recorder, Paper Chart
Cardiovascular	§870.2850, II	DRS	Extravascular blood pressure transducer.
General Hospital	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Anesthesiology	§868.1400, II	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Anesthesiology	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
Anesthesiology	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
Anesthesiology	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
Anesthesiology	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
Anesthesiology	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.)
Anesthesiology	§868.1700, II	CBR	Analyzer, Gas, Nitrous-Oxide, Gaseous Phase (Anesthetic Conc.)
Anesthesiology	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
Anesthesiology	§868.2775, II	KOI	Electrical peripheral nerve stimulator.
Neurology	§882.1400, II	OLW	Index-Generating Electroencephalograph Software
Neurology	§882.1400, II	OLT	Non-normalizing quantitative electroencephalograph software
Neurology	§882.1400, II	OMC	Reduced-montage standard electroencephalograph
Neurology	§882.1400, II	ORT	Burst suppression detection software for electroencephalograph

### 3. Predicate device

K213799 - BeneVision N series Patient Monitors (including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22), Shenzhen Mindray Bio-medical Electronics Co., LTD.

### 4. Reference devices

K211619 - Multi-Parameter Patient Monitor, Shenzhen Comen Medical Instruments Co., LTD.

K193242 - Masimo Radical-7 Pulse CO-Oximeter and Accessories, Masimo Corporation.

K123043 - IRMA - Infrared Mainstream Gas Analyzer, Phasein AB.

K171121 - Masimo Root Monitoring system and accessories, Masimo Corporation.

K042601 - Respironics Novamatrix LLC, Capnostat CO<sub>2</sub>.

K103604 - ISA – infrared Sidestream gas Analyzer, Phasein AB.

K040183 - BISX, Aspect medical systems Inc.

K102084 - STIM POD NMS450 Nerve Stimulator, XAVANT TECHNOLOGY(PTY) LTD.

K231160 - Cardio Q50, Cardio Q70, Bionet Co., Ltd.

### 5. Device Description

There are six (6) models under evaluation, namely N10, N12, N15, N10MPro, N12MPro, N15MPro. All models share the same intended condition of use, the same intended patient population and operator profile, biological safety characteristic and principle of operation. All these models are the same on electric and electrical circuit and components, mechanical construction, software and alarm system. The only difference lies on the screen and configuration of with/without plug-in module slot and the number of battery packs.

### 6. Indications for Use

The N10, N12, N15, N10MPro, N12MPro, NM15Pro Multi-parameter Patient Monitors are intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, and 12-lead selectable), Arrhythmia Analysis, ST Segment Analysis, QT Analysis, Heart Rate (HR) and Heart-Rate-Variability(HRV), interpretations of resting 12-lead ECG, Respiration rate (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO<sub>2</sub>), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), and Carbon Dioxide (CO<sub>2</sub>). The N10MPro, N12MPro, NM15Pro Multi-parameter Patient Monitors are also intended for monitoring, displaying, reviewing, storing, alarming and transferring of physiological parameters including Masimo Rainbow SpO<sub>2</sub>, Anesthesia gas (AG), oxygen (O<sub>2</sub>) respiratory gas monitoring, Bispectral Index (BIS), Respiration Mechanics (RM), and Neuromuscular Transmission Monitoring (NMT). All the parameters can be monitored on a single adult, pediatric, or

neonatal patient except for the following:

- Arrhythmia analysis is intended to use on adult patients only and is not intended and shall not be used on pediatric and neonatal population.
- NIBP measurement continual mode is not applicable to neonates.
- When using COMEN SpO<sub>2</sub>, the monitor is intended to be used on adult patient only.
- PAWP is intended for adult and pediatric patients only.
- C.O. measurement is intended for adult patients only.
- BIS monitoring is intended for adult patients only.
- RM is intended for adult and pediatric patients only.
- NMT monitoring is intended for adult and pediatric patients only.

The monitors are to be used in healthcare facilities by healthcare professionals or under their guidance.

The Multi-parameter Patient monitors are not intended for emergency and transport use, aircraft environment, or home use.

The monitors are not intended for use as apnea monitors.

The monitors are not intended for use in MRI or CT environments.

The monitors are not intended for use on patients who have a demonstrated need for cardiac monitoring known arrhythmias of VT, Accelerated Idioventricular rhythm and Torsades de Pointes.

Please note the following use limitations:

- The ECG analysis result is not intended to be the sole means of diagnostics for conditions such as prolongation of the QT interval, syndrome associated with torsades de pointes (TDP), etc. It is offered to the clinicians on an advisory basis in conjunction with the clinicians' knowledge of the ECG pattern, patient background, clinical history, symptoms and other diagnostic information.
- The clinical use of QT interval measured by the subject device should not replace a trained clinician using diagnostic 12-lead ECG in a clinical environment.
- The clinical significance of the ST level change information should always be determined by clinicians. This feature is intended to aid the clinicians in monitoring the change in ST only and not for diagnosis of STEMI or ischemia events.
- The patient monitor provides a HRV parameter which is only a mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis including but not limited to, predicting sudden cardiac death and evaluating the pathological state related to the activity and balance of cardiac autonomic nerves.

## 7. Technological Comparison to Predicate Devices

Both the subject device and the predicate device provide a means for monitoring a patient, collecting specific physiological data, processing the data for alarm conditions and display numeric values and waveforms. In terms of indications for use, N series patient monitors are a subset of the predicate devices indications except for inclusion of the Masimo rainbow SpO<sub>2</sub>. Although this feature is not present in the predicate devices, it is presented in the Masimo Radical-7 Pulse CO-Oximeter and Accessories (K193242, Masimo Corporation) reference device.

Both the subject devices and predicate devices can provide monitoring such as ECG(3-lead, 5-lead or 12-

lead selectable arrhythmia analysis, ST segment analysis, QT analysis, heart rate (HR) and Heart-Rate-Variability(HRV), Respiration rate(Resp), Temperature (Temp), SpO<sub>2</sub>, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), PAWP, cardiac output (C.O.), carbon dioxide (CO<sub>2</sub>), Oxygen (O<sub>2</sub>), anesthetic gas (AG), Bispectral index (BIS), Respiration Mechanics (RM) and Neuromuscular Transmission Monitoring (NMT), and provide an interpretations of resting 12-lead ECG for a single patient.

The N10, N12, N15, N10MPro, N12MPro, NM15Pro Patient Monitors restricted the use of arrhythmia analysis, BIS monitoring and COMEN SpO<sub>2</sub> on adults only, which is a subset of BeneVision N series patient monitor. These do not affect the substantial equivalence of subject device and predicate device.

Table below compares the key technological features of the subject devices to the predicate device (K213799). The features in gray are different between the predicate devices and the subject devices.

Table 2: Device Comparison Table

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
1.	Model	BeneVision N22/ N19/N17/N15/N12	N10/ N12/ N15/ N10MPro/ N12MPro/NM15Pro
2.	Power	Battery or AC power	Battery or AC power
3.	requirements	100 to 240 Va.c. ( $\pm 10\%$ ), 50/60 Hz ( $\pm 3$ Hz) N22/N19: 2.8 A to 1.6 A N17/N15/N12: 2.0 A to 0.9 A	100-240V-, 50/60Hz N10, N12, N10MPro, N12MPro: 1-0.5A N15, N15MPro: 1.5-0.75A
4.	Battery	N22/N19: Rechargeable lithium-ion battery, 10.8 V/ 5600 mAh N17/N15/N12: Rechargeable lithium-ion battery, 10.95 V/4500mAh	Standard rechargeable Lithium-ion battery: 10.8V /2500mAh for N10,N10MPro, N12, N12MPro; 10.8V/5000mAh for N15, N15MPro Optional rechargeable Lithium-ion battery: 10.8V /5000mAh
5.	Data storage	N22/ N19: Solid State Hard Drive(SDD) N17/ N15/N12: Embedded Multi Media Card (eMMC).	Embedded Multi Media Card (eMMC).
6.	Data Recorder	N22/ N19: Supports the thermal recorder module, needs to be plugged in the SMR. N17/ N15/N12: Supports the thermal recorder module and the built-in thermal recorder, but they cannot work at the same time.	Supports internal thermal recorder.
7.	Alarm system	The alarm lamp will light cyan, yellow, or red depending on alarm type.	The alarm indicator light are cyan, yellow, or red depending on alarm priority.
8.	ECG	3-lead, 5-lead, 6-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J point Auto detection, Dual Channel Pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR). interpretations of resting 12-lead ECG	Support 3-lead, 5-lead, 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J point Auto detection, single Channel Pace detection, Multi-lead ECG synchronization analysis, Heart Rate and Heart Rate variability (HRV), interpretations of resting 12-lead ECG

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
9.		HR measurement range: 15~350 bpm (neonate, pediatric), 15~300 bpm(adult);	HR measurement range: Adult: 15-300 bpm, Neonate/pediatric:15-350 bpm
10.		HR accuracy: ±1 bpm or ±1%, whichever is greater.	HR accuracy: ±1 bpm or ±1%, whichever is greater.
11.		QT/QTc Measurement range: 200 to 800 ms	QT/QTc Measurement range: 200ms - 800ms
12.		QT Measurement accuracy: ±30 ms	QT Measurement accuracy: ±30ms
13.		ST measurement Range: -2.0 mV to +2.0 mV RTI	ST measurement Range: -2.5mV-+2.5mV (-25.0 mm-+25.0 mm)
14.		ST measurement Accuracy: -0.8 mV- +0.8 mV: ±0.02 mV or ±10%, whichever is greater Other range: not specified	ST measurement Accuracy: -0.8mV-+0.8mV; measurement error: ±0.02mV or ±10%, whichever is greater; Other range: not defined
15.		Respiration	Method: Trans-thoracic impedance
16.		Measurement range: Adult: 0 to 120 rpm Pediatric, neonate: 0 to 150 rpm	Measurement range: Adult: 7-120rpm Pediatrics: 7-150rpm Neonate: 7-150rpm
17.		Accuracy: 7 to 150 rpm: ±2 rpm or ±2%, whichever is greater 0 to 6 rpm: not specified	Accuracy: ±2 rpm
18.	SpO <sub>2</sub>	Support Mindray SpO <sub>2</sub> , Masimo SpO <sub>2</sub> , Nellcor SpO <sub>2</sub> modules	Support COMEN SpO <sub>2</sub> , Masimo SpO <sub>2</sub> , Masimo Rainbow SpO <sub>2</sub> , Nellcor SpO <sub>2</sub> modules
19.		Mindray SpO <sub>2s</sub> range: 0-100 %	COMEN SpO <sub>2</sub> range: 0% - 100%
20.		Mindray SpO <sub>2</sub> accuracy: 70%-100%: ±2% ABS(Adult/pediatric); 70%-100%: ±3%	COMEN SpO <sub>2</sub> accuracy: 70% - 100%: ±3% in Adult mode (non-motion),

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		ABS (neonate); 0-69%: not specified.	Within rang 0% - 69%: not defined.
21.		Masimo SpO <sub>2</sub> range: 1% - 100%	Masimo SpO <sub>2</sub> range: 1% - 100%
22.		Masimo SpO <sub>2</sub> accuracy: 70 to 100%: ±2%ABS (adult/pediatric, without motion) 70 to 100%: ±3%ABS (adult/pediatric, with motion) 70 to 100%: ±3%ABS (neonate) 1% to 69%: Not specified.	Masimo SpO <sub>2</sub> accuracy: 70% - 100%SpO <sub>2</sub> : ±2% in Adu./Ped. Mode (non-motion), ±3% in Adu./Ped. mode (during motion) ±3% in Neo. mode (motion and non-motion); within range 1% - 69%: not defined.
23.		Nellcor SpO <sub>2</sub> range: 0 to 100%	Nellcor SpO <sub>2</sub> range: 0% - 100%
24.		Nellcor SpO <sub>2</sub> accuracy: 70 to 100%: ±2%ABS (adult/pediatric) 70 to 100%: ±3%ABS (neonate) 0 to 69%: Not specified	Nellcor SpO <sub>2</sub> accuracy: 70% - 100%SpO <sub>2</sub> : ±2% in Adu./Ped. mode (non-motion) ±3% in Neo. mode (non-motion); within range 0% - 69%: not defined.
25.		Not supported	Masimo Rainbow SpO <sub>2</sub> (only for NMPro series model)
26.	PR	PR from SpO <sub>2</sub> Range: 20-254 bpm Accuracy: ±3 bpm	PR from SpO <sub>2</sub> Range: 20bpm-300bpm Accuracy: ±2bpm
27.		PR from Masimo SpO <sub>2</sub> Range: 25 to 240 bpm Accuracy: ±3 bpm (without motion) ±5 bpm (with motion)	PR from Masimo SpO <sub>2</sub> Range: 25bpm-240bpm Accuracy: ±3bpm (non-motion) or ±5bpm (during motion)
28.		PR form Nellcor SpO <sub>2</sub> Range: 20 to 300 bpm Accuracy: 20 to 250 bpm: ±3 bpm 251 to 300 bpm: not specified	PR form Nellcor SpO <sub>2</sub> Range: 20bpm-300bpm Accuracy: 20bpm-250bpm: ±3bpm; 251 bpm-300 bpm: not defined
29.		PR form Masimo Rainbow SpO <sub>2</sub> (Only for NMPro Series models)	PR form Masimo Rainbow SpO <sub>2</sub> (Only for NMPro Series models)

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		Range: not supported Accuracy: not supported	Range: 25bpm-240bpm Accuracy: $\pm 3$ bpm
30.		PR from NIBP Range: 30 to 300 bpm Accuracy: $\pm 3$ bpm or $\pm 3\%$ , whichever is greater	PR from NIBP Range: 30bpm-300bpm Accuracy: $\pm 3$ bpm or $\pm 3\%$ , whichever is greater.
31.		PR from IBP Range: 25 to 350 bpm Accuracy: $\pm 1$ bpm or $\pm 1\%$ , whichever is greater	PR from IBP Range: 25bpm-350bpm Accuracy: $\pm 1$ bpm or $\pm 1\%$ , whichever is greater
32.	Temperature	Thermal resistance, Direct mode	Thermal resistance, Direct mode
33.		Range: 0 to 50 °C (32 to 122 °F)	Range: 0°C -50°C (32°F-122°F)
34.		Accuracy: $\pm 0.1$ °C or $\pm 0.2$ °F (without probe error)	Accuracy: $\pm 0.1$ °C ( $\pm 0.2$ °F) (main unit)
35.	CO <sub>2</sub>	Method: Infrared absorption	Method: Infrared absorption
36.		Support using Mindray sidestream CO <sub>2</sub> module, Mindray AG module or third-party CO <sub>2</sub> modules, microstream module and mainstream module.	Support using Masimo mainstream/sidestream CO <sub>2</sub> module, Respironics mainstream CO <sub>2</sub> module
37.	CO <sub>2</sub> module (Mainstream)	Mindray Mainstream CO <sub>2</sub> module Range: 0-150mmHg	Masimo CO <sub>2</sub> module (Mainstream) Range: 0 - 190mmHg / 0 - 25.3 kPa / 0 - 25.0% (at 760mmHg)
38.		Accuracy: Mainstream EtCO <sub>2</sub> module 0-40mmHg: $\pm 2$ mmHg, 41-70mmHg: $\pm 5\%$ of the reading, 71-100mmHg: $\pm 8\%$ of the reading, 101-150mmHg: $\pm 10\%$ of the reading;	Accuracy: Under all conditions: 0 - 114mmHg: $\pm (2.25$ mmHg +4% of reading); 115 mmHg - 190 mmHg: not defined Standard environment (22°C $\pm 5$ °C and 1013 $\pm 40$ hPa): 0 - 114 mmHg: $\pm (1.52$ mmHg +2% of reading); 115 -190 mmHg: not defined;

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
39.	CO <sub>2</sub> module (Sidestream)	awRR range: 0-150rpm	awRR range: 0 - 150 breaths/min. measured at I/E ratio 1:1
40.		awRR accuracy: ±1rpm	awRR accuracy: ±1rpm
41.		Mindray Sidestream CO <sub>2</sub> module: Range: 0-150mmHg Mindray Microstream CO <sub>2</sub> module: Range: 0 to 99 mmHg	Masimo CO <sub>2</sub> module(Sidestream) Range: 0 - 190mmHg / 0 - 25.3 kPa/ 0 - 25.0% (at 760mmHg)
42.		Accuracy: Mindray Sidestream CO <sub>2</sub> module: Full accuracy mode: 0 - 40 mmHg: ±2mmHg 41 - 76 mmHg: ±5% of reading 77 - 99 mmHg: ±10% of reading 100 - 150 mmHg: ±(3mmHg + 8% of reading ISO accuracy mode: Add ±2mmHg to the full accuracy mode Mindray Microstream CO <sub>2</sub> module 0 to 38 mmHg: ±2 mmHg 39 to 99 mmHg: ±5% of the reading (0.08% of the reading increased in error for every 1 mmHg if the reading is more than 38 mmHg)	Accuracy: Masimo Capno sidestream: All conditions: 0 - 114mmHg: ± (2.25mmHg +4% of reading) 115 - 190 mmHg: not defined  Standard conditions (22°C±5°C and 1013±40 hPa) 0-114 mmHg: ± (1.52mmHg +2% of reading) 114 - 190 mmHg: not defined
43.		awRR range: 0 to 150 rpm	awRR range: 0 - 150 breaths/min. measured at I/E ratio 1:1
44.		awRR accuracy: Mindray Sidestream CO <sub>2</sub> module ≤60 rpm: ±1 rpm; 61 to 150 rpm: ±2 rpm Mindray Mircostream CO <sub>2</sub> module 0 to 70 rpm: ±1 rpm; 71 to 120 rpm: ±2 rpm; 121 to 150 rpm:	awRR accuracy: ±1rpm

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		±3 rpm	
45.	CO <sub>2</sub> (Mainstream)	Mindray Mainstream CO <sub>2</sub> module: Range: 0-150mmHg	Respironics CO <sub>2</sub> (Mainstream) Range: 0 - 150 mmHg, 0% - 19.7%, 0 - 20.0kPa (at 760mmHg)
46.		Accuracy: Mindray Mainstream CO <sub>2</sub> module: 0-40mmHg: ±2mmHg, 41-70mmHg: ±5% of the reading, 71-100mmHg: ±8% of the reading, 101-150mmHg: ±10% of the reading;	Accuracy: 0 - 40 mmHg: ±2mmHg 41 - 70mmHg: ±5% of reading; 71 - 100mmHg: ±8% of reading; 101 - 150 mmHg: ±10% of reading; Note: temperature at 35°C
47.		Mindray Mainstream CO <sub>2</sub> module: awRR Range: 0-150rpm	awRR Range: 0rpm, 2rpm - 150rpm
48.		Mindray Mainstream CO <sub>2</sub> module: awRR Accuracy: ±1rpm	awRR Accuracy: ±1 rpm
49.	NIBP	Adult: Systolic: 25mmHg to 290mmHg Diastolic: 10mmHg to 250mmHg Mean: 15mmHg to 260mmHg	Adult mode: SYS: 25mmHg - 290mmHg (3.3kPa-38.7kPa) DIA: 10mmHg - 250mmHg (1.3kPa-33.3kPa)
50.		Pediatrics Systolic: 25mmHg to 240mmHg Diastolic: 10mmHg to 200mmHg Mean: 15mmHg to 215mmHg	Pediatrics mode: SYS: 25mmHg - 240mmHg (3.3kPa-33.3kPa) DIA: 10mmHg - 200mmHg (1.3kPa-28.0kPa)
51.		Neonatal Systolic: 25mmHg to 140mmHg Diastolic: 10mmHg to 115mmHg Mean: 15mmHg to 215mmHg	Neonatal mode: SYS: 25mmHg - 140mmHg (3.3kPa-18.7kPa) DIA: 10mmHg - 115mmHg (1.3kPa-15.3kPa)
52.	IBP	Direct invasive measurement	Direct invasive measurement

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function	The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function
53.		Range: -50 to 300 mmHg	Range: -50mmHg-+370mmHg (-6.6kPa-+49.3kPa)
54.		Accuracy: $\pm 2\%$ or $\pm 1$ mmHg, whichever is greater (without sensor)	Accuracy: $\pm 1$ mmHg or $\pm 2\%$ , whichever is greater (sensor error excluded);
55.	C.O.	Thermodilution method	Thermodilution method
56.		C.O. Range: 0.1 to 20 L/min Accuracy: $\pm 5\%$ or $\pm 0.1$ L/min, whichever is greater	C.O. Range: 0.1-20l/min Accuracy: $\pm 5\%$ or $\pm 0.1$ l/min, whichever is greater
57.		BT: Range: 23 to 43 °C Accuracy: $\pm 0.1$ °C (excluding sensor)	BT: Range: 23-43°C (73°F-109°F) Accuracy: $\pm 0.1$ °C ( $\pm 0.2$ °F) (main unit)
58.		IT: Range: 0 to 27 °C Accuracy: $\pm 0.1$ °C (excluding sensor)	IT: Range: 0-27°C Accuracy: $\pm 0.1$ °C (sensor excluded)
59.	AG (only in NMPro series models)	Infrared absorption, paramagnetic properties for O <sub>2</sub> monitoring	Infrared absorption, paramagnetic properties for O <sub>2</sub> monitoring
60.		Gas type: CO <sub>2</sub> , N <sub>2</sub> O, O <sub>2</sub> , Des., Iso., Enf., Sev., Hal	Gas type: CO <sub>2</sub> , O <sub>2</sub> , N <sub>2</sub> O, one of the five anesthetic gases (Enf, Iso, Sev, Hal, DES)
61.		CO <sub>2</sub> Range: 0 to 30% Accuracy: $0 \leq \text{CO}_2 \leq 1$ : $\pm 0.1\%$ ABS $1 < \text{CO}_2 \leq 5$ : $\pm 0.2\%$ ABS $5 < \text{CO}_2 \leq 7$ : $\pm 0.3\%$ ABS $7 < \text{CO}_2 \leq 10$ : $\pm 0.5\%$ ABS	CO <sub>2</sub> Range: 0%-25% Accuracy: 0%-15%: $\pm(2\%+2\%*\text{reading})$ ; 15%-25%: Not defined.

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		CO <sub>2</sub> >10: Not specified	
62.		N <sub>2</sub> O Range: 0 to 100% Accuracy: 0≤N <sub>2</sub> O≤20: ±2%ABS 20<N <sub>2</sub> O≤100: ±3%ABS	N <sub>2</sub> O Range: 0%-100% Accuracy: ±(2%+2%*reading)
63.		Enf, Iso, hal Range: 0 to 30% Accuracy: 0 to 1: ±0.15%ABS 1 to 5: ±0.2%ABS >5: not specified	Enf, Iso, hal Range: 0%-25% Accuracy: 0%-8%: ±(0.15%+5%*reading); 8%-25%: not defined.
64.		Sev Range: 0 to 30% Accuracy: 0 to 1: ±0.15%ABS 1 to 5: ±0.2%ABS 5 to 8: ±0.4%ABS >8: not specified	Sev Range: 0%-25% Accuracy: 0%-10%: ±(0.15%+5%*reading); 10%-25%: not defined
65.		DES Range: 0 to 30% Accuracy: 0 to 1: ±0.15%ABS 1 to 5: ±0.2%ABS 5 to 10: ±0.4%ABS 10 to 15: ±0.6%ABS 15 to 18: ±1%ABS >18: Not specified	DES Range: 0%-25% Accuracy: 0%-22%: ±(0.15%+5%*reading); 22%-25%: not defined.
66.		O <sub>2</sub>	O <sub>2</sub>

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		Range: 0 to 100% Accuracy: 0 to 25: $\pm 1\%$ ABS; 25 to 80: $\pm 2\%$ ABS[ 80 to 100: $\pm 3\%$ ABS	Range: 0%-100% Accuracy: $\pm(1\%+2\%*\text{reading})$
67.		awRR: Range: 2-100 rpm Accuracy: 2 to 60 rpm: $\pm 1$ rpm >60 rpm: not specified	awRR: Range: 0rpm-150rpm Accuracy: $\pm 1$ rpm
68.	BIS (only for NMPPro series models)	Bispectral index	Bispectral index
69.		Measurement parameters: BIS, SQI, EMG, SR, SEF, TP, BC, sBIS, sEMG, ASYM	Measurement parameters: BIS, SQI, EMG,SR
70.		BIS, BIS L, BIS R: 0 to 100	BIS: 0-100
71.		SQI, SQI L, SQI R: 0 to 100%	SQI: 0-100%
72.		EMG, EMG L, EMG R: 0 to 100 dB	EMG: 0-100dB.
73.		SR, SR L, SR R: 0 to 100%	SR: 0-100%
74.		sBIS L, sBIS R: 0 to 10.0 SEF, SEF L, SEF R: 0.5 to 30.0 Hz TP, TP L, TP R: 40 to 100 dB BC, BC L, BC R: 0 to 30 sEMG L, sEMG R: 0 to 10.0 ASYM: 0 to 100%	Not supported
75.	RM (only in NMPPro series modelsr)	FLOW: Adult/Pediatric: $\pm(2-120)$ L/min; Infant: $\pm (0.5$ to 30) L/min PAW: -20-120 cmH <sub>2</sub> O; MVe/MVi:	Flow: Adult/pediatric: $\pm(2-120)$ L/min; Infant: $\pm (0.5$ to 30) L/min Paw: -20-120 cmH <sub>2</sub> O; Pmean:-20-120 cmH <sub>2</sub> O;

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		Adult/Pediatric: 2-60L/min; Infant: 0.5 to 15 L/min TVe/TVi: Adult/Pediatric: 100-1500ml; Infant: 20 to 500ml Calculated Parameters: awRR:4-120rpm; I:E:4:1-1:8; FEV1.0: 0-100%; Pmean:0-120 cmH <sub>2</sub> O; PEEP:0-120 cmH <sub>2</sub> O; PIP: 0-120 cmH <sub>2</sub> O; Pplat:0-120 cmH <sub>2</sub> O; PEF:2-120L/min; PIF:2-120L/min; Compl: 0-200ml/ cmH <sub>2</sub> O; RSBI:0-4095rpm/L;	PEEP:-20-120 cmH <sub>2</sub> O; PIP: -20-120 cmH <sub>2</sub> O; Pplat:-20-120 cmH <sub>2</sub> O; PEF:2-120L/min; PIF:2-120L/min; Inspiratory tidal volume (TVi) /Expiratory tidal volume (TVe): Adult/pediatric: 100-1500ml; Infant: 20-500ml, Inspired minute volume (MVi)/Expired minute volume (MVe): Adult/pediatric: 2-60 L/min; Infant: 0.5-15 L/min, Respiration rate (RR): 4-120 rpm I:E: 2:1-1:4.5 First second forced expiratory volume ratio (FEV1.0): 0-100% Compliance (Cstat/Cdyn): 4-100ml/ cmH <sub>2</sub> O; Rapid Shallow Breathing Index (RSBI): 0-200 rpm/l
76.		Flow: Adult/Pediatric: 1.2L/min or ±10% of reading, whichever is greater; Infant: 0.5 L/min or ±10% of the reading, whichever is greater PAW: ±3% of reading; MVe/MVi: ±10% of reading; TVe/TVi: Adult/Pediatric: ±15ml or ±10% of reading, whichever is greater; Infant: ±6 ml or ±10%×reading, whichever is greater	Flow: Adu./Ped.: ±1.2l/min or ±10% of actual reading, which is greater Infant. ±0.5l/min or ±10% of actual reading, which is greater Airway Pressure (Paw): ±1 cmH <sub>2</sub> O ±3% of actual reading, which is greater PEEP, PIP, Pmean, Pplat: ±1 cmH <sub>2</sub> O or ±3% of actual reading, which is greater Inspiratory tidal volume (TVi), Expiratory tidal volume

No.	Feature	Predicate Device <b>BeneVision N series Patient Monitors (K213799),</b>	Subject Device <b>N series Patient Monitor</b>
		Calculated Parameters: awRR:4-99rpm: $\pm 1$ rpm, 100-120rpm, $\pm 2$ rpm; I:E: not specified; FEV1.0: not specified; Pmean: $\pm 10\%$ ; PEEP: not specified; PEF: $\pm 10\%$ ; PIF: $\pm 10\%$ ; PIP: $\pm 10\%$ ; Pplat: not specified; Compl: not specified; RSBI: not specified;	(TVe): Adu./Ped.: $\pm 15$ ml or $\pm 10\%$ of actual reading, which is greater Infant: $\pm 6$ ml or $\pm 10\%$ of actual reading, which is greater Inspired minute volume (MV <sub>i</sub> ), Expired minute volume (MV <sub>e</sub> ): $\pm 10\%$ of actual reading Respiration rate (RR): 4 rpm - 99 rpm.: $\pm 1$ rpm; 100rpm-120rpm.: $\pm 2$ rpm I:E, First second forced expiratory volume ratio (FEV1.0), Compliance (Cstat/Cdyn), Rapid Shallow Breathing Index (RSBI): not defined.
77.	NMT (only in NMTPro series models)	Measurement range: ST-Ratio: 0 to 200% TOF-Count: 0 to 4 TOF-Ratio: 5% to 160% TOF-T1%: 0 to 200% DBS-Count: 0 to 2 DBS-Ratio: 5% to 160% PTC-Count: 0 to 20	Measurement range: ST-Ratio: 0 to 200% TOF-Count: 0 to 4 TOF-Ratio: 5% to 160% TOF-T1%: 0 to 200% DBS-Count: 0 to 2 DBS-Ratio: 5% to 160% PTC-Count: 0 to 20

## 8. Performance Data

To establish the substantial equivalence of N10, N12, N15, N10MPro, N12MPro and N15MPro Patient Monitors, functional and system level testing was conducted on the subject device. The testing showed that the devices meet specifications and the performance level is equivalent to the predicate.

### Software and Cybersecurity Verification and Validation Testing

Software testing included software design, development, verification, validation, and traceability. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

Patient safety and security risks have been addressed in the design and development of the subject device including a Security Risk Assessment and Threat model, which is mapped to the General Principles and Security Capabilities as outlined in FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". The subject device has been through rigorous testing for cybersecurity vulnerability including penetration testing and code review with acceptable results. The cybersecurity controls will be monitored and updated throughout the device lifecycle.

### Biocompatibility Testing

Biocompatibility testing was performed on the subject device components in accordance with the FDA guidance on the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Issued: September 4, 2020).

### Usability study

Usability evaluation including critical task identification through Use-Related Risk Analysis (URRA), human factors (HF) validation testing and other activities had been completed for the proposed patient monitor. All use-related hazards have been considered and adequately mitigated and that the residual risks are acceptable.

### Bench test

The N10, N12, N15, N10MPro, N12MPro and N15MPro Patient Monitors have been tested and found to be in compliance with the following safety, performance and electromagnetic compatibility standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2 Edition 4.1: 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TS 60601-4-2 Edition 1.0:2024-03 Medical electrical equipment-Part 4-2: Guidance and interpretation-Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

- IEC 60601-1-6 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ANSI AMI IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021] Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems [Including Amendment 2 (2021)]
- ANSI AAMI IEC 60601-2-25:2011/(R)2016 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- ANSI AAMI IEC 60601-2-27:2011(R)2016 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34 Edition 4.0 2024-10 Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-55 Second edition 2018-02 [Including AMD 1:2023] Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- IEC 81001-5-1 Edition 1.0 2021-12 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
- ANSI AAMI EC53:2013/(R)2020 ECG trunk cables and patient leadwires
- ANSI AAMI EC 57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- IEC 60601-2-40:2024 Medical electrical equipment –Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- IEC 80601-2-49:2018+A1:2024 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
- IEC 80601-2-26:2019+A1:2024 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- ISO 14971 Third Edition 2019-12 Application of Risk Management To Medical Devices

## 9. Clinical Studies

The subject device incorporates clinical subsystem modules for SpO<sub>2</sub> monitoring (including OEM module), respiratory rate measurement, and NIBP measurement. For these features, new clinical accuracy validation testing was not necessary because these subsystems along with their accessories have been previously validated and cleared. This 510(k) leverages the previous clinical accuracy data, as shown in Table 3, for the clinical functionalities in the subject device.

Table 3: Clinical Accuracy Data

Monitoring subsystem	Physiological monitoring unit		Subsystem Cleared in 510(k)	
	Technology	Component	510K number	Device name/ manufacturer
SpO <sub>2</sub> monitoring	Masimo	Module, Algorithm	K053269	Masimo SET Rad-8 Pulse Oximeter, Model Rad-8, Kestrel/ Masimo Corporation
		Sensor cable extender (interconnection cable)	K053269	Masimo SET Rad-8 Pulse Oximeter, Model Rad-8, Kestrel/ Masimo Corporation
		Probes	K051212 K111888 K180046 K101896	Masimo Rad-97 and Accessories/ Masimo Corporation
Masimo Rainbow SpO <sub>2</sub> monitoring	Masimo	Module, Algorithm	K193242	Masimo Radical-7 Pulse CO-Oximeter and Accessories/ Masimo Corporation
		Sensor cable extender (interconnection cable)	K080238	MASIMO RAINBOW SET RADICAL 7 PULSE CO-OXIMETER, MASIMO RAINBOW SET RAD 87 PULSE CO-OXIMETER
		Probes	K081659 K080238	RAINBOW ADHESIVE CO-OXIMETRY SENSOR, MODELS RI-25-L, RI-25, RI-20 AND RI-20-L
SpO <sub>2</sub> monitoring	Nellcor	Module, Algorithm	K060576	OxiMax Pulse Oximetry System with N-600x Pulse Oximeter and

Monitoring subsystem	Physiological monitoring unit		Subsystem Cleared in 510(k)	
	Technology	Component	510K number	Device name/ manufacturer
				OxiMax Sensors and Cables/ Nellcor Puritan Bennett Incorporated
		Sensor cable extender (interconnection cable)	K060576	OxiMax Pulse Oximetry System with N-600x Pulse Oximeter and OxiMax Sensors and Cables/ Nellcor Puritan Bennett Incorporated
		Probes	K012891	OxiMax Pulse Oximetry System with N-595x Pulse Oximeter and OxiMax Sensors and Cables/ Nellcor Puritan Bennett Incorporated
SpO <sub>2</sub> monitoring	COMEN	Module, Algorithm	K211619	Shenzhen COMEN NC10 NC12 multi-parameter patient monitor / Shenzhen Comen Medical Instruments Co., Ltd.
		Sensor cable extender (interconnection cable)	K211619	Shenzhen COMEN NC10 NC12 multi-parameter patient monitor / Shenzhen Comen Medical Instruments Co., Ltd.
		Probes	K211619	Shenzhen COMEN NC10 NC12 multi-parameter patient monitor / Shenzhen Comen Medical Instruments Co., Ltd.
NIBP	COMEN	Module,	K211619	Shenzhen COMEN

Monitoring subsystem	Physiological monitoring unit		Subsystem Cleared in 510(k)		
	Technology	Component	510K number	Device name/ manufacturer	
measurement		Algorithm		NC10 NC12 multi-parameter monitor / Shenzhen Comen Medical Instruments Co., Ltd.	patient
		NIBP hose and Cuff	K211619	Shenzhen COMEN NC10 NC12 multi-parameter monitor / Shenzhen Comen Medical Instruments Co., Ltd.	patient
Respiratory rate measurement	COMEN	Module, Algorithm	K211619	Shenzhen COMEN NC10 NC12 multi-parameter monitor / Shenzhen Comen Medical Instruments Co., Ltd.	patient
	Masimo Mainstream and Sidestream CO <sub>2</sub> module	Module, Algorithm and accessories	K123043	IRMA - Infrared Mainstream Gas Analyzer/Masimo Corporation	
	Respironics Mainstream CO <sub>2</sub> module	Module, Algorithm and accessories	K042601	Capnostat CO <sub>2</sub> /Respironics Novamatrix LLC,	

## ECG

The performance of the ECG arrhythmia analysis algorithm has been comprehensively evaluated using standard, expert-annotated ECG databases (i.e., AHA, MIT-BIH, NST, CU, ESC, QT database, MIT-BIH Malignant Ventricular Fibrillation Database, MIT-BIH Supraventricular Arrhythmia Database(MIT-SV), MIT-BIH ST Change Database, MIT-BIH Atrial Fibrillation Database (AFDB), INCART Database, Long Term AF Database (LTAfDB), Apnea-ECG Database, Sudden Cardiac Death Holter Database, MGH/MF Waveform Database, Long-Term ST Database, Comen Pacemaker Database and Comen supraventricular Arrhythmia database) in accordance with the requirements of AAMI/ANSI EC57:2012 “Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms”.

## **10. Conclusion**

The N10, N12, N15, N10MPro, N12MPro and N15MPro Multi-parameter Patient Monitor are equivalent to the predicate device, the BeneVision N series Patient Monitors, (K213799), in terms of indications for use and technological characteristics. Performance testing and compliance with FDA-recognized consensus standards demonstrate that the N10, N12, N15, N10MPro, N12MPro and N15MPro Patient Monitors are as safe and effective as the predicate device.

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